the trademark Puregene®. Furthermore, claim 45 has been amended. Thus, claims 46-48 are now valid.

In the Claims

Delete claims 8, 18, 29, 39, 50 and 60.

The amended claims are as follows:

1. A method for isolating DNA from a biological sample comprising the following sequential steps:

(a) separating the biological material comprising DNA from the remainder of the biological sample;

(b) contacting the separated biological material comprising DNA of step (a) with a hypertonic, high salt reagent so as to form a suspension of said biological material containing DNA;

(c) contacting the suspension of step (b) with a lysis reagent to form a lysate comprising DNA and non-DNA biological components released from the biological material; and

(d) separating the DNA from the non-DNA biological components in the lysate of step (c) to yield isolated DNA.

2. A method for isolating DNA from a biological sample comprising biological material comprising DNA comprising the following sequential steps:

(a) contacting the biological material comprising DNA with a hypertonic, high salt reagent so as to form a suspension of the biological material comprising DNA;

(b) contacting the suspension of step (b) with a lysis reagent to form a lysate comprising DNA and non-DNA biological components released from the biological material; and

(c) separating the DNA from the non-DNA biological components in the lysate of step (c) to yield isolated DNA.

4. The method of claim 1 or 2, wherein the biological sample comprises a virus.

24. A method for isolating DNA from a biological sample comprising cells comprising the following sequential steps:

(a) separating the cells comprising DNA from the remainder of the biological sample;

(b) contacting the separated cells comprising DNA of step (a) with a hypertonic, high salt reagent so as to form a suspension of said biological cells;

(c) contacting the suspension of step (b) with a lysis reagent to form a lysate comprising DNA and non-DNA biological components of the biological material; and

(d) separating the DNA from the non-DNA biological components of the lysate of step (c) to yield isolated DNA.

45. A method for isolating DNA from a biological sample comprising red blood cells and white blood cells comprising the following sequential steps:

(a) contacting the biological sample with a red blood lysis reagent to lyse the red blood cells;

(b) separating the white blood cells from the lysed red blood cells;

(c) contacting the white blood cells with a hypertonic, high-salt reagent to suspend the white blood cells in a solution of said hypertonic, high-salt reagent;

(d) subsequently contacting the white blood cells of step (c) with a lysis reagent to form a lysate containing DNA and non-DNA cellular material; and

(e) separating the DNA from non-DNA cellular material of the lysate to yield isolated DNA.

35 USC 112

Item 4A. Claims 8, 18, 29, 39, 50, and 60 contains the trademark/trade name Puregene®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade

name is used to identify/describe the reagents for the isolation of DNA and, accordingly, the identification/description is indefinite.

It is respectfully pointed out to the Examiner that the amendments to the claim overcome this rejection.

Item 4B. Claim 4, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim recites "biological sample is a virus", which is indefinite and unclear because it is not clear whether the biological sample consists only of virus or a virus is isolated from a biological sample comprising said virus. Amendment to recite the specific biological sample would obviate the rejection.

It is respectfully pointed out to the Examiner that the amendments to the claim overcome this rejection.

Item 4C. Claim 45 recites the limitation "biological sample" in isolating DNA from a whole blood sample. There is insufficient antecedent basis for this limitation in the claim. Claim 45 is limited to whole blood sample and not a biological sample. If this limitation refers to whole blood sample, the dependent claim 47 is confusing because the method steps of claim 45 appear to be drawn to a whole blood sample an not to bone marrow sample. Further the dependent claim 46 is also confusing because if the biological sample is elected from body fluids, the method steps of claim 45 appear to be drawn to whole blood and not to body fluids in claim 46. Amendment to specify the sample would obviate the rejection.

It is respectfully pointed out to the Examiner that the amendments to the claim overcome this rejection.

Item 4D. Claims 1-46, 48-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant independent claims 1-2, 24, and 45 recite a term "physically" in the context of separating the DNA, which is indefinite and unclear. It is not clear whether physically refers to by hand, by centrifugation, by electrophoresis, by elution or by chromatographic separation. Amendment to specify the separation means would obviate the rejection.

It is respectfully pointed out to the Examiner that the amendments to the claim overcome this rejection.

35 USC 102

Item 5A. Claims 1-2, 7-9, 17-24, 28-30, 38-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Heath et al. (Arch. Pathol. Lab. Med., Vol. 125, pp. 127-133, January 2001).

It is respectfully pointed out to the Examiner that the present invention is a sequential separation of DNA from biological material as indicated in the claims and specification. Furthermore, mouthwash is not the hypertonic high-salt solution of the invention.

Item 5B. Claims 1-3, 6-7, 9-13, 19-22, 24-25, 27-28, 30-34, 40-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Schneider (USPN. 5,596,092).

It is respectfully pointed out to the Examiner that the present invention is a sequential separation of DNA from biological material as indicated in the claims and specification. In contrast, Schneider teaches the lysis of the biological material first.

Item 5C. Claims 1-3, 6-7, 9-16, 19-25, 27-28, 30-37, 40-46, 48, 49, 51-58, and 61-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Gray et al. (USPN. 5,777,098).

It is respectfully pointed out to the Examiner that the present invention is a sequential separation of DNA from biological material as indicated in the claims and specification. In contrast, Gray teaches the lysis of the biological material first.

Item 5D. Claims 1-4, 9-16, 30-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Henco et al. (USPN. 5,057,426).

It is respectfully pointed out to the Examiner that the present invention is a sequential separation of DNA from biological material as indicated in the claims and specification. In contrast, Henco teaches the lysis of the biological material first.

Item 5E. Claims 1-3, 5-6, 13-16, 19-21, 24-28, 34-37, 40-42, 55-58, 63 are rejected under 35 U.S.C. 102(e) as being anticipated by Fairman (Pub No. US 2002/0068280).

It is respectfully pointed out to the Examiner that the present invention is a sequential separation of DNA from biological material as indicated in the claims and specification. In contrast, Fairman teaches the lysis of the biological material first.

35 USC 103

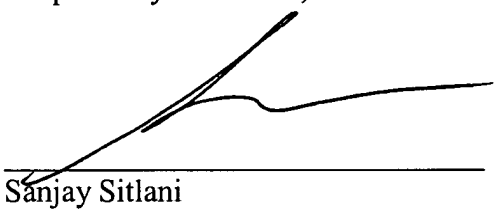
Item 6A. Claims 50, 59-60, 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. (USPN. 5,777,098). in view of Heath et al. (Arch. Pathol. Lab. Med., Vol. 125, pp. 127-133, January 2001).

It is respectfully pointed out to the Examiner that the present invention is a sequential separation of DNA from biological material as indicated in the claims and specification. In contrast, Gray teaches the lysis of the biological material first. Furthermore, Gray does not suggest teaching the use of a hypertonic reagent before that of the lysing reagent.

Based on the amendments and remarks above, applicant believes all pending claims are in condition for allowance.

If the Examiner believes that a conference would be of value in expediting the prosecution of this application, the Examiner is hereby invited to telephone undersigned counsel to arrange for such a conference.

Respectfully submitted,



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Sanjay Sitlani
Registration No. 48,489
ROPES & GRAY
700 12th Street, NW, Suite 900
Washington, D.C. 20005
Tel: (202) 508-4618
Fax: (202) 508-4650